From: McClintic, Howard [McClintH@ctc.com]

Sent: 4/27/2018 2:38:16 PM

To: Woods, Clint [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=bc65010f5c2e48f4bc2aa050db50d198-Woods, Clin]

Subject: Agreeing with the Controversial Transparency Rule

Attachments: ATT00001.txt; FINAL one page LNT project summary 10-24-17.docx; FINAL LNT Presentation of Howard

McClintic.pptx



Ensuring the Future Through Innovation, Science and Technology

2711 Jefferson Davis Hwy,, Suite 620 Arlington, VA 22202 (703) 310-5688 (703) 310-5655 FAX

at

(202) 689-4586 Mobile

E-Mail: McClintH@ctc.com

Good Morning Mr. Woods,

My colleague, Dr. Robert (Bob) Golden and I knew that this Transparency Rule was coming and cheer its arrival – Bravo!

Nonetheless, I am haunted when I read the Administrator's urging: that the rule **be lasting**! There is *only one way* for this important tectonic change to meet and that is it **be mandated** by a newly formulated, independent Committee of the National Academy of Sciences (NAS). When undertaking their literature review, the NAS Committee Members and Staff will uncover a recently released, peer reviewed, highly credentialed, science-based Report that makes plain that there is a wealth of

toxicological and epidemiology data for chemicals and radiation that will readily yield reproducible as well as transparent regulations.

Administrator Pruitt is unique in recognizing that the mathematical construct that the EPA uses for assessing risk, the linear no-threshold (LNT) methodology, is of **MOST** questionable scientific validity. The LNT model was originally adopted by the National Academy of Sciences (NAS) in 1956 for radiation and in 1977 for chemicals. Because LNT-driven regulations, whether for chemicals or radiation, have, for many years, been claimed to be science-based (see

(https://science.house.gov/sites/republicans.science.house.gov/files/documents/HHRG-113-SY-20131114-SD001%20.pdf as well as http://www.c-span.org/video/?327016-1/epa-administrator-gina-mccarthy-testimony-proposed-regulations), the underlying scientific foundation for such regulations, particularly the LNT model itself, should also, by definition, reflect empirical data. If such scientific data are lacking, as they are for the LNT model, science-based regulatory methodologies (including benefit-cost analyses) for both chemicals and radiation should be updated to reflect significant advancements in scientific knowledge.

Besides introducing you to the fact that the *CTC Foundation* has empaneled a prestigious Science Committee that comprised of 15 individuals in the fields of toxicology, radiation biology, evolutionary biology, epidemiology, risk assessment, and economics; the Committee is preparing its FINAL Report that will demonstrate that there is no scientific support for the LNT model

and that ample modern data (NOT threshold models) should be the bases for regulations. In particular, the abundant data generated as part of the Department of Energy's 10 year, \$200 million Low Dose Radiation Research Program (LDRRP) will be a central element of the anticipated publication. Collectively, these and other complementary data have elucidated the cellular defense mechanisms by which humans can withstand exposure to low dose radiation without adverse effects.

I have begun to encourage the "doctors in the US Senate" (Barrasso [R-WY] and Cassidy [R-LA]) to introduce and progress legislation in the Senate that would be a companion bill to H.R. 4675, pertaining to the low dose radiation research that Doctor and US Congressman Roger Marshall (R-KS) championed. There are some modifications that Dr. Robert (Bob) Golden and I would advocate, given our respective professional experiences working at NAS, but more on that later. Our overarching Goal is shared: a paradigm shift whereby a **lasting**, scientifically valid approach for radiation and chemical risk assessment as well as for economic benefit-cost analyses be achieved.

Thank you for your time and interest.

Most sincerely yours,

Howard

Howard G. McClintic Executive Director

https://www.washingtonpost.com/news/energyenvironment/wp/2018/04/24/pruitt-to-unveil-controversialtransparency-rule-limiting-what-research-epa-canuse/?noredirect=on&utm_term=.4f5c21b67c8c

Pruitt unveils controversial 'transparency' rule limiting what

research EPA can use

by Juliet Eilperin and Brady Dennis by Juliet Eilperin and Brady Dennis Email the author Energy and Environment April 24 at 6:09 PM Email the author



Environmental Protection Agency Administrator Scott Pruitt moved Tuesday to limit what science can be used in writing agency regulations, a change long sought by conservatives.

The proposed rule would only allow the EPA to consider studies where the underlying data is made available publicly. Such restrictions could affect how the agency protects Americans from toxic chemicals, air pollution and other health risks.

Pruitt and proponents describe the new approach as an advance for transparency, one that will increase Americans' trust and

confidence in the research on which EPA decisions are based. "Today is a red-letter day," he told a group of supporters at agency headquarters. "The science that we use is going to be transparent. It's going to be **reproducible**."

But a chorus of scientists and public health groups warn that the rule would effectively block the EPA from relying on long-standing, landmark studies on the harmful effects of air pollution and pesticide exposure. Such research often involves confidential personal or medical histories or proprietary information.

The move reflects a broader effort already underway to shift how the EPA conducts and uses science to guide its work. Pruitt has upended the standards for who can serve on its advisory committees, barring scientists who received agency grants for their research while still allowing those funded by industry.

His announcement Tuesday came as the administrator faces increasing heat for ethics and management decisions — from both sides of the political aisle, with even President Trump privately voicing more concern over the growing number of allegations. Pruitt only focused on the proposed rule during his remarks, saying his agency was "taking responsibility for how we do our work and respecting process."

He made clear he intends the new requirements to be lasting ones. "This is not a policy," he said. "This is not a memo."

The proposal will be subject to a 30-day comment period, EPA officials said. Scientific organizations are already campaigning to

block the rule from being finalized. Based on previous court cases, it could prompt legal challenges if implemented.

Former EPA administrator Gina McCarthy said that requiring the kind of disclosure Pruitt envisions would have disqualified the federal government from tapping groundbreaking research, such as studies linking exposure to leaded gasoline to neurological damage or a major 1993 study by Harvard University that established the link between fine-particle air pollution and premature deaths.

Scientists often collect personal data from subjects but pledge to keep it confidential. Researchers will have trouble recruiting study participants if the rule is enacted, she predicted, even if they pledge to redact private information before handing it over to the government.

"The best studies follow individuals over time, so that you can control all the factors except for the ones you're measuring," said McCarthy, who now directs the Center for Health and the Global Environment at Harvard's public health school. "But it means following people's personal history, their medical history. And nobody would want somebody to expose all of their private information."

House Science Committee Chairman Rep. Lamar Smith (R-Tex.), who was with Pruitt during his announcement Tuesday, has for years sought to establish a similar requirement. His 2017 legislation, titled the Honest and Open New EPA Science Treatment Act, failed to pass both chambers.

Pruitt and Smith met at EPA headquarters on Jan. 9, according to Pruitt's public calendar, and an email obtained under the Freedom of Information Act indicates that the lawmaker pressed the administrator to adopt the legislation's goal as his own.

Smith made "his pitch that EPA internally implement the HONEST Act [so that] no regulation can go into effect unless the scientific data is publicly available for review," Aaron Ringel, deputy associate administrator for congressional affairs at the EPA, wrote other agency staffers. His email was obtained by the Union of Concerned Scientists, a scientific advocacy organization.

Conservatives, such as Trump EPA transition team member Steve Milloy, have long tried to discredit independent research the agency used to justify limiting air pollution from burning coal and other fossil fuels. A series of studies has shown that fine particulate matter, often referred to as soot, enters the lungs and bloodstream and can cause illnesses such as asthma and even premature death.

"During the Obama administration, the EPA wantonly destroyed 94 percent of the market value of the coal industry, killed thousands of coal mining jobs and wreaked havoc on coal mining families and communities," Milloy said in a statement, "all based on data the EPA and its taxpayer-funded university researchers have been hiding from the public and Congress for more than 20 years."

While the administration presses ahead, legal experts warn that the rule may be vulnerable to a court challenge. In unanimous decisions in 2002 and 2010, the U.S. Court of Appeals for the District of Columbia Circuit said the EPA is not legally obligated to obtain and publicize the data underlying the research it considers in crafting regulations.

In the 2002 case, brought by the American Trucking Associations, two judges appointed by Ronald Reagan and one named by Bill Clinton wrote that they agreed with the agency that such a requirement "would be impractical and unnecessary." The government's defense had noted that "EPA's reliance on published scientific studies without obtaining and reviewing the underlying data is not only reasonable, it is the only workable approach."

A range of scientific organizations are already campaigning to block the rule from being finalized. On Monday, 985 scientists signed a letter organized by the Union of Concerned Scientists, urging Pruitt not to forge ahead with the policy change.

"There are ways to improve transparency in the decision-making process, but restricting the use of science would improve neither transparency nor the quality of EPA decision-making," they wrote. "If fully implemented, this proposal would greatly weaken EPA's ability to comprehensively consider the scientific evidence across the full array of health studies."

Under the proposed rule, third parties would be able to test and try to replicate the findings of studies submitted to the EPA. But, the scientists wrote, "many public health studies cannot be replicated, as doing so would require intentionally and unethically exposing people and the environment to harmful contaminants or recreating one-time events."

Gretchen Goldman, an expert on air pollution and research director for the organization's Center for Science and Democracy, said the rule could put some scientists in a quandary: Keeping personal health data or propriety information private would mean having their work ignored by the EPA.

"We have this incredible science-based process that works, and it has worked, by and large, even in the face of tremendous political pressures to not go with a science-based decision," Goldman said.

The Environmental Protection Network, a group of former EPA employees, issued a report Tuesday stating that many older studies — in which the original data sets were either not maintained or stored in outdated formats — would be eliminated under the proposed rule.

And while there is no estimate yet for how much it would cost EPA to obtain and disseminate studies' underlying data, the Congressional Budget Office has projected that Smith's measure, if enacted, would cost the agency \$250 million for initial compliance and then between \$1 million and \$100 million annually. A 2015 CBO analysis estimated that EPA would cut the number of studies it relies on by half because of the bill's requirements.

Geophysicist Marcia McNutt, who is president of the National Academy of Sciences, said Tuesday that she is concerned the rule would prevent the EPA from relying on the best available scientific evidence.

"This decision seems hasty," she wrote in an email. "I would be fearful that the very foundations of clean air and clean water could be undermined."

Yet the American Chemistry Council praised Pruitt's effort. "Our industry is committed to working with EPA to help ensure the final rule increases transparency and public confidence in the agency's regulations," its statement said, "while protecting personal privacy, confidential business information, proprietary interest and intellectual property rights."

Joel Achenbach and Dino Grandoni contributed to this report.

This message and any files transmitted within are intended solely for the addressee or its representative and may contain company sensitive information. If you are not the intended recipient, notify the sender immediately and delete this message. Publication, reproduction, forwarding, or content disclosure is prohibited without the consent of the original sender and may be unlawful.

Concurrent Technologies Corporation and its Affiliates.

www.ctc.com 1-800-282-4392